CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF TOXIC SUBSTANCES CONTROL

Final Decision to Re-Certify
Hazardous Waste Environmental Technology

The California Environmental Protection Agency, Department of Toxic Substances Control (DTSC) has reached a final decision to re-certify the following hazardous waste environmental technology:

The SCIGEN NEUTRALEX technology for treating formaldehyde in waste neutral buffered Formalin from histopathology specimen preservation and use of automated histopathology tissue processors.

Applicant: SCIGEN, Inc.
333 East Gardena Blvd
Gardena, California 90249

Section 25200.1.5., Health and Safety Code, enacted by Assembly Bill 2060, authorizes DTSC to certify the performance of hazardous waste environmental technologies. Only technologies which are determined to not pose a significant potential hazard to the public health and safety or to the environment when used under specified operating conditions may be certified. Incineration technologies are explicitly excluded from the certification program.

The purpose of the certification program is to provide an independent technical evaluation of technologies to identify those meeting applicable quality standards, so as to facilitate regulatory and end-user acceptance and to promote and foster growth of California's environmental technology industry.

DTSC makes no express or implied warranties as to the performance of the manufacturer's product or equipment. The end-user is solely responsible for complying with the applicable federal, state, and local regulatory requirements. Certification does not limit DTSC's authority to require additional measures for protection of public health and the environment.

By accepting certification, the manufacturer assumes, for the duration of certification, responsibility for maintaining the quality of the manufactured equipment and materials and their operation at a level equal to or better than was provided to obtain certification and agrees to be subject to quality monitoring by DTSC as required by the statute under which certification is granted.

DTSC proposed the re-certification decision in the June 23, 2000 California Regulatory Notice Register (Register 2000 No. 25-Z), subject to a 30-day public review and comment period. Written comments were submitted to DTSC. All comments received were considered and appropriate changes made prior to publishing this final decision. The principal comments focused on (1) whether the materials safety data sheet (MSDS) for NEUTRALEX should list each ingredient, or whether the ingredients can be considered proprietary and the properties of the mixture reported as a whole; and (2) whether sodium metabisulfite, one ingredient in NEUTRALEX, may pose a health hazard or may result in the generation of sulfur dioxide gas. The California Occupational Safety and Health Administration (cal/OSHA) is currently reviewing the MSDS with regards to whether the specific ingredients are proprietary. SCIGEN will update the MSDS to incorporate any necessary changes determined by Cal/OSHA. With regards to the safety of sodium metabisulfite, DTSC was aware of the

presence of this material in the formulation during its original evaluation. NEUTRALEX is formulated to include excess neutral buffers to prevent acidic conditions under which sulfur dioxide may be formed. In addition, specific conditions in the certification require that the treatment be conducted in a hood or other well-ventilated area, that users use adequate eye, face, and hand protection, and that all end users are properly trained. DTSC has determined that the original certification language provides conditions under which the technology can be operated safely and effectively.

Additional information supporting DTSC's final decision, including DTSC's responses to comments received, are available for review. Requests for additional information concerning this final decision should be submitted to the following address:

California Environmental Protection Agency
Department of Toxic Substances Control
Office of Pollution Prevention and Technology Development
P.O. Box 806
1001 I Street, 12th Floor
Sacramento, California 95812-0806
Attn: Dr. Bruce La Belle (916) 324-2958
http://www.dtsc.ca.gov/sppt/pptd/td/techcert.html

Background

The Scigen Neutralex technology was originally certified for a three-year term, effective June 29, 1997. The final decision to certify was published in the May 30, 1997, California Regulatory Notice Register, Volume 97, Number 22-Z. Scigen has not changed their technology since the original certification was issued. The final decision published on May 30, 1997, includes a description of the technology, the certification statement and associated conditions and limitations, and the technical basis for the original certification decision. A copy of this information may be obtained from DTSC. The information is also available on the DTSC web site at:
http://www.dtsc.ca.gov/sppt/pptd/td/techcert.html

Basis for Re-Certification

Scigen stated in their application for re-certification that the Neutralex technology has not changed since it was originally certified. DTSC staff contacted three users of the Neutralex technology to gather information on its performance during the period of certification. A pathology laboratory contacted uses Neutralex to treat approximately 1 gallon of formalin waste per day, primarily from automated tissue processors (ATP waste). A Kaiser Permanente regional pathology laboratory treats approximately 4 gallons of per day of wastes from ATP and decantate from tissue specimens. Stanford University treats approximately 100 - 140 gallons per month from tissue processors, gross pathology specimen preservation, and decanting of pre-filled pathology specimen containers. Each of the users stated that the Neutralex technology worked well. None had experienced problems with the technology. One of the users had been inspected by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and two by the College of American Pathologists (CAP). One of the users had been inspected by their Certified Unified Program Agency (CUPA). None of the inspectors had identified problems with the treatment operations.

Independent of the re-certification evaluation for Scigen, DTSC staff conducted a field test of two other formaldehyde treatment technologies. Neutralex was used a baseline for testing. As part of this separate evaluation of formaldehyde treatment technologies, DTSC staff tested ten 10% NBF samples for pre- and post-treatment formaldehyde concentrations and provided aliquots of the samples to an independent laboratory for pre-and post-treatment acute aquatic LC_{50} determinations. The pre-treatment formaldehyde concentrations as determined by U.S. EPA Method 8315 ranged from 41,000 to 48,000 mg/L, while the post-treatment concentrations ranged from 320 to 820 mg/L. The pre-treatment LC_{50} concentrations ranged from 505 to 574 mg/L, while the post-treatment LC_{50} concentrations were all greater than 750 mg/L. These results are consistent with DTSC's conclusion that the technology is safe and reliable.

Regulatory Considerations

Title 22, California Code of Regulations, Section 67450.20, specifies that treatment of formaldehyde by health care facilities using any technology certified as effective for that purpose is authorized for operation under a grant of conditional exemption. The treatment must be operated pursuant to the conditions imposed on the certification. In addition, the generator conducting the treatment must comply with the conditions of the Conditional Exemption in Section 25201.5 of the Health and Safety Code. The reader should refer to these statutory and regulatory sections for additional information.

Certification Reference

As a holder of a valid hazardous waste environmental technology certification, Scigen is authorized to use the certification seal (California Registered Service Mark Number 046720) during the term of the certification. Scigen shall cite the certification number and date of issuance in conjunction with the certification seal whenever it is used.

When providing information on the certification to an interested party, Scigen shall at a minimum provide the full text of the original and re-certification decisions as published in the May 30, 1997, and May 11, 2001, California Regulatory Notice Registers.

Duration of the Certification

This re-certification will become effective on June 10, 2001, and remain in effect for the period of three years from that date, unless it is revoked for cause or amended.